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APR 19 2006

S/N 10/020,786

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SIMMONS ET AL.	Examiner:	G. LEFFERS
Serial No.:	10/020,786	Group Art Unit:	1636
Filed:	DECEMBER 13, 2001	Docket No.:	11669.183USU1
Confirmation No.	9525	Customer No.	23552
Title:	PROKARYOTICALLY PRODUCED ANTIBODIES AND USES THEREOF		

CERTIFICATE UNDER 37 CFR 1.6(d):

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on April 19, 2006.

By: Elizabeth Lane  
Name:

**REQUEST FOR RECONSIDERATION OF DECISION REGARDING  
PATENT TERM ADJUSTMENT MAILED MARCH 31, 2006 AND  
REQUEST FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Mail Stop Patent Ext  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby request reconsideration of the patent term adjustment indicated on the face of patent, U.S. Pat. No. 6,979,556 that issued on December 27, 2005, from the above-identified application. Please charge our Deposit Account No. 13-2725 in the amount of \$200.00 as set forth in 37 C.F.R. § 1.18(e) for the petition fee. This request for reconsideration is timely in accordance with the 30-day response period indicated in the Decision Regarding Patent Term Adjustment mailed March 31, 2006.

Statement of the Facts

1. The face of the issued patent indicates a patent term adjustment of 157 days. Applicants respectfully submit that a patent term adjustment of 221 days is indicated by the Rules.

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2. 37 C.F.R. § 1.704(d) states that a paper containing only an information disclosure statement in compliance with 37 C.F.R. § 1.97 and 1.98 will not be considered a failure to engage in reasonable efforts to conclude prosecution of the application under 37 C.F.R. § 1.704c(8), if the IDS shows that each item of information contained in the statement was first cited in a communication from a foreign patent office in a counterpart application, and that this communication was not received by any individual designated in 1.56(c) more than 30 days prior to the filing of the IDS.

3. Applicants submitted a Supplemental Information Disclosure Statement (IDS) on April 23, 2004 by express mail that cited a single reference, Lo et al., on a Form 1449. The Patent Office indicated receipt of the IDS on April 23, 2004. The IDS explicitly asserts that the Form 1449 contains references that "were recently cited in an International Search Report mailed March 24, 2004." Applicants also enclosed a copy of the foreign patent office communication (i.e., an International Preliminary Examination Report). The communication states that it relates to Applicant file reference "P1793R1" (see top of page 1), which matches the attorney docket number listed on the filing receipt in the present application that was mailed on January 28, 2002. The single reference cited on the Form 1449 (Lo et al.) at issue was listed as newly cited in this foreign communication (see page 3 of the IPER under the heading "NEW CITATIONS"). Therefore, the Applicants submit that the Supplemental IDS was clearly filed within 30 days of receipt of a communication from a foreign patent office by any individual within the scope of 1.56(c), and clearly contained only references that had been first cited in a counterpart foreign application. See Exhibit A.

4. For the foregoing reasons, Applicants respectfully submit that each item contained on the IDS of April 23, 2004 was first cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than 30 days prior to filing the IDS.

5. Applicants respectfully submit that the IDS filed on April 23, 2004, falls within the scope of the exemption provided by 37 C.F.R. § 1.704(d), and therefore is not an "other paper" under 37 C.F.R. § 1.704c(8). Nevertheless, the Patent Term Adjustment History displayed on the PAIR system for this application indicates that Applicants incurred a delay of 64 days resulting from the filing of this IDS. Applicants respectfully submit that this result is erroneous, such that the PTA for this application should be increased by 64 days, for a total of 221 days.

6. Applicants acknowledge that the present Petition relates to events that occurred prior to payment of the issue fee. Applicants submit, however, that prior to payment of the issue fee, they were not entitled to an adjustment of the PTA since, even disregarding the 64 day delay, Applicants' total delay of 158 days (33 + 67 + 58 days as shown on PAIR) exceeded the total delays caused by the Patent Office. Subsequent to payment of the issue fee, however, the Patent Office incurred an additional delay under 37 CFR 1.702(a)(4) and 702(b) resulting in an overall delay of 379 days as indicated by PAIR, which exceeds Applicants' total delay by an amount more than the 64 days at issue in this Petition. Applicants submit, therefore, that the delays incurred by the Patent Office after payment of the issue fee now entitle Applicants to an adjustment of 64 days that was unavailable when the issue fee was paid. Consequently, the present after-issuance Petition is timely, since it relates to issues that could not have been raised under 37 CFR 1.705(b). See 37 CFR 1.705(d).

7. Applicants submit that the present application is not subject to a terminal disclaimer.

8. It is Applicants' belief that there were no additional circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704, beyond the circumstances already indicated on the PAIR Patent Term Adjustment History and reflected in the 157 days of PTA currently granted to the present application.

9. For the foregoing reasons, Applicants respectfully request that the term of the U.S. Patent 6,979,556 be extended by an additional 64 days, resulting in a total PTA of 221 days, and that a Certificate of Correction be issued to that effect.

10. If there are any outstanding issues or a need for any clarification on this matter, the Patent Office is invited to telephone the undersigned attorney.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903

Date: April 19, 2006

Katherine M. Kowalchuk  
Katherine M. Kowalchuk  
Reg. No. 36,848  
KMK:sab

23552

PATENT TRADEMARK OFFICE

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

Elizabeth Tauer

  
Signature

4/19-06  
Date

**EXHIBIT A**  
**U.S. SERIAL NO. 10/020,786**  
**IDS DOCUMENTS SUBMITTED ON APRIL 23, 2004**

Receipt is hereby acknowledged for the following in the U.S. Patent and Trademark Office:  
In re Application of: SIMMONS ET AL.  
For: PROKARYOTICALLY PRODUCED ANTIBODIES & USES THEREOF  
Docket No.: 11669.183USU1  
Filed: DECEMBER 13, 2001  
Express Mail No.: EV 372668234 US  
Date Mailed: April 23, 2004  
Serial No.: 10/020,786  
Due Date:

☒ Transmittal Sheet in duplicate containing Certificate of Mailing  
☒ Supplemental Information Disclosure Statement, Form 1449, 1 Reference, Copy of International Search Report  
☒ Check in the amount of \$180.00 for information disclosure statement fee  
☒ Return postcard

Patent

KKowalchuk:sab

Receipt is hereby acknowledged for the following in the U.S. Patent and Trademark Office:  
In re Application of: SIMMONS ET AL.  
For: PROKARYOTICALLY PRODUCED ANTIBODIES & USES THEREOF  
Docket No.: 11669.183USU1  
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☒ Supplemental Information Disclosure Statement, Form 1449, 1 Reference, Copy of International Search Report  
☒ Check in the amount of \$180.00 for information disclosure statement fee  
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KKowalchuk:sab





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Express Mail Corporate Acct. No. <b>X551464</b>				Federal Agency Acct. No. or Postal Service Acct. No.			
<b>FROM: (PLEASE PRINT)</b> <b>12 332 5300</b> <b>MERCHANT &amp; GOULD</b> <b>80 S 8TH ST STE 3200</b> <b>MINNEAPOLIS MN 55402-5336</b> <b>11669.1834USU1</b> <b>KKowalchuk :sob</b>				<b>TO: (PLEASE PRINT)</b> <b>MAIL STOP PATENT APPLICATION</b> <b>COMMISSIONER FOR PATENTS</b> <b>PO BOX 1450</b> <b>ALEXANDRIA VA 22313-1450</b>			

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Express Mail Corporate Acct. No. <b>X551464</b>				Federal Agency Acct. No. or Postal Service Acct. No.			
<b>FROM: (PLEASE PRINT)</b> <b>12 332 5300</b> <b>MERCHANT &amp; GOULD</b> <b>80 S 8TH ST STE 3200</b> <b>MINNEAPOLIS MN 55402-5336</b> <b>11669.1834USU1</b> <b>KKowalchuk :sob</b>				<b>TO: (PLEASE PRINT)</b> <b>MAIL STOP PATENT APPLICATION</b> <b>COMMISSIONER FOR PATENTS</b> <b>PO BOX 1450</b> <b>ALEXANDRIA VA 22313-1450</b>			

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MERCHANT & GOULD

009/019

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MERCHANT & GOULD P.C.

Director of the United States Patent and Trademark Office

Two Signatures Required For Amounts Exceeding \$5,000

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424533 075906003 00001 93270

PAGE 9/19 \* RCVD AT 4/19/2006 3:55:30 PM [Eastern Daylight Time] \* SVR:USPTO-EFXXF-3/4 \* DNIS:2738300 \* CSID:6123329081 \* DURATION (mm-ss):05-24



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	SIMMONS ET AL.	Examiner:	G. LEFFERS
Serial No.:	10/020,786	Group Art Unit:	1636
Filed:	DECEMBER 13, 2001	Docket:	11669.183USU1
Confirmation No.:	9525	Customer No.:	23552
Title:	PROKARYOTICALLY PRODUCED ANTIBODIES & USES THEREOF		

**CERTIFICATE UNDER 37 CFR 1.10:**

"Express Mail" mailing label number: EV 372668234 US  
Date of Deposit: April 23, 2004

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

Name: Sheryl A. Bocboom

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**23552**

PATENT TRADEMARK OFFICE

Sir:


We are transmitting herewith the attached:

**EV372668234US**

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Supplemental Information Disclosure Statement, Form 1449, 1 Reference, Copy of International Search Report
- ☒ Check in the amount of \$180.00 for information disclosure statement fee
- ☒ Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C.  
P.O. Box 2903, Minneapolis, MN 55402-0903  
612.332.5300

By:   
Name: Katherine M. Kowalchuk  
Reg. No.: 36,848  
KKowalchuk:sab

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APR 19 2006

S/N 10/020,786

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	SIMMONS ET AL.	Examiner:	G. LEFFERS
Serial No.:	10/020,786	Group Art Unit:	1636
Filed:	DECEMBER 13, 2001	Docket No.:	11669.183USU1
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Title:	PROKARYOTICALLY PRODUCED ANTIBODIES & USES THEREOF		

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"Express Mail" mailing label number: EV 372668234 US  
Date of Deposit: April 23, 2004

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:   
Name: Cheryl K. Boerboom

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c))

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. At least some of the references were recently cited in an International Search Report mailed March 24, 2004.

This statement should be considered because it is submitted after the mailing date of a first Office Action on-the-merits or a first Office Action after filing a Request for Continued Examination under 37 C.F.R. § 1.114 or a CPA under 37 C.F.R. § 1.53(d), but before the mailing date of: i) a final action under 37 C.F.R. § 1.113; ii) a Notice of Allowance under 37 C.F.R. § 1.311; or iii) an action that otherwise closes prosecution on the application. Enclosed is a check in the amount of \$180.00 under 37 C.F.R. § 1.17(p) for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided. Enclosed for the Examiner's information is a copy of the International Search Report.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

Date:

April 23, 2004

Katherine M. Kowalchuk  
Katherine M. Kowalchuk  
Reg. No. 36,848  
KMK:sab

**23552**

PATENT TRADEMARK OFFICE

Date Mailed: April 23, 2004

Sheet 1 of 1

<b>FORM 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b>  <b>IN AN APPLICATION</b>  (Use several sheets if necessary)	<b>Docket Number:</b> 11669.183USU1	<b>Application Number:</b> 10/020,786
	<b>Applicant:</b> SIMMONS ET AL.	
	<b>Filing Date:</b> DECEMBER 13, 2001	<b>Group Art Unit:</b> 1636

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Lo, K. et al., "Expression and secretion of an assembled tetrameric CH2-deleted antibody in <i>E. coli</i> ", <u>Hum. Antibod. Hybridomas</u> , 3:123-128 (July 1992)
		Copy of International Search Report dated March 24, 2004

**23552**

PATENT TRADEMARK OFFICE

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

\*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
STEVEN X. CUI  
C/O GENENTECH, INC.  
MS 49  
1 DNA WAY  
SOUTH SAN FRANCISCO, CA 94080-4990

PCT

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

24 MAR 2004

Applicant's or agent's file reference

P1793R1

## IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US01/48691

13 December 2001 (13.12.2001)

14 December 2000 (14.12.2000)

Applicant

GENENTECH, INC.

MAR 30 2004

GENENTECH, INC.  
LEGAL DEPT.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

CALENDARED/LS/EC

Send Copy of IPER to  
National Phase ASSOCS. ID - 15 APR 04

DUE DATE

and

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
Facsimile No. (703) 305-3230

Authorized officer

Gerard G. Belfers Jr., PhD

Telephone No. (703) 308-0196

Form PCT/IPEA/416 (July 2003)

CALENDARED/LS/TM

IDS Due - 30 Days - P1793R1 US

23 APR 04

PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P1793R.1		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/48691	International filing date (day/month/year) 13 December 2001 (13.12.2001)	Priority date (day/month/year) 14 December 2000 (14.12.2000)	
International Patent Classification (IPC) or national classification and IPC IPC(7): C12N 15/13, 15/70; C07K 16/00, 19/00; A61K 47/48 and US Cl.: 435/69.1, 69.7, 320.1, 252.3, 471; 435/23.1; 530/387.1			
Applicant GENENTECH, INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>17</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 13 June 2002 (13.06.2002)		Date of completion of this report 08 March 2004 (08.03.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>Gerald C. Leffers Jr., PhD</i> Telephone No. (703) 308-0196	

Form PCT/IPEA/409 (cover sheet) (July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/US06/0691

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-72 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages 73-76 as originally filed  
pages NONE as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages 1-21 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(e)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

Form PCT/IP/EA/409 (Box I) (July 1998)

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

 Internat<sup>n</sup> Application No.  
 PCT/US 4891

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**
**1. STATEMENT**

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-2, 4, 6-12, 14, 16-19, 21-23, 26, 28, 30, 32 and 36-41 lack novelty under PCT Article 33(2) as being anticipated by Lo et al.

Lo et al teach the expression and secretion of an assembled tetrameric CH2-deleted antibody in E. coli. (i.e. JM105; see materials/methods). The CH2-deleted antibody, 14, 18, has been previously shown to be potentially useful in radioimmunoassay of human tumors. The bacterial expression vector contains a discistronic unit comprised of an L-chain cDNA and a CH2-deleted H-chain cDNA where the natural signal peptides of the H and L chains were replaced with the signal peptide of the bacterial protein pectate lyase B. When expressed in the JM105 host under control of the trp-lac promoter, the products were secreted into the growth-media in a properly folded and active form.

Claims 3, 5, 13, 15, 20, 24-25, 27, 29, 31 and 33-35 lack an inventive step under PCT Article 33(3) as being obvious over LO et al.

The teachings of Lo et al are described above. The limitations recited in these claims are all functional equivalents of those taught in the Lo et al reference. For example, it would have been prima facie obvious to the ordinary skilled artisan to substitute any bacterial promoter known in the art for trp-lac promoter taught in the reference or any known bacterial secretion signal. Similarly, it would have been prima facie obvious to use known E. coli strains lacking degP or other proteolytic activities.

Claims 1-41 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

**NEW CITATIONS**

LO et al. Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in E. coli. Human Antibodies Hybridomas. July 1992, Vol. 3, pages 123-128.

Form PCT/ISA/409 (Box V) (July 1998)



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Internal application No.  
PCT/US01/48691

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

## V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 3, 5, 13, 15, 20, 24-25, 27, 29, 31, 33-35

The opinion as to Novelty was negative (No) with respect to claims 1-2, 4, 6-12, 14, 16-19, 21-23, 26, 28, 30, 32, 36-41

The opinion as to Inventive Step was positive (Yes) with respect to claims NONE

The opinion as to Inventive Step was negative (NO) with respect to claims 1-41

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-41

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

Form PCT/IP/EA/409 (Continuation Sheet) (July 1998)

## PATENT COOPERATION TREATY

## PCT

## NOTE OF INFORMAL COMMUNICATION WITH THE APPLICANT

(PCT Rule 66.6)

International application No. PCT/US01/48691	Applicant's or agent's file reference P1793R1	Date of informal communication (day/month/year)
Applicant GENENTECH, INC.		

<u>Communication</u> <input checked="" type="checkbox"/> by telephone <input type="checkbox"/> personal	<u>Participants</u> <input checked="" type="checkbox"/> Applicant: GENENTECH, INC. <input checked="" type="checkbox"/> Agent: Paul Naik <input checked="" type="checkbox"/> Examiner(s): Gerald G. Leffers Jr.	<input checked="" type="checkbox"/> Identity checked <input checked="" type="checkbox"/> authorization checked <input type="checkbox"/> personally known
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Summary of communication:

Mr. Naik agreed to sending a preliminary examination report (PCT 409) instead of a written opinion (PCT 408) due to the fact that the opinion and report are overdue.

☐ An extension of time limit is granted (Form PCT/IPEA/427).

☒ A copy of this note is being sent to the applicant with Form PCT/IPEA/429.

PCT/IPEA/424.

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 Form PCT/IPEA/428 (July 1992)	Authorized officer Gerald G. Leffers Jr., PhD Telephone No. (703) 308-0196
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